Legal

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Compliance

4298 Elysian Fields Avenue
New Orleans, LA 70122

April 26, 1995

WARNING LETTER NO. 44-5

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jivn Ren Chen, President
5408 Interstate Drive
Sage Pharmaceuticals, Inc.
Shreveport, LA 71109

Dear Mr. Chen:

During an inspection of your drug manufacturing firm located at 5408 Interstate Drive, Shreveport, Louisiana conducted on 1/30/95 through 3/8/95, our investigator documented deviations from the Good Manufacturing Practices Regulations, Title 21, Code of Federal Regulations (CFR), Part 211 causing your products to be adulterated within the meaning of 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act.

These deviations included:

(1) failure to adequately validate the manufacturing process for your drug products [21 CFR 211.110(a)];

(2) failure to thoroughly investigate, evaluate and document batches of drug products failing to meet specifications [21 CFR 211.192];

(3) failure to assay [redacted] and [redacted] products for strength of each active ingredient prior to release [21 CFR 211.165(a)];

(4) failure to record and justify changes in written procedures in the manufacture of [redacted], lot # [redacted], [redacted] lot # [redacted], and [redacted] tablets lot # [redacted] and # [redacted] [21 CFR 211.100(b)];

(5) failure to establish written procedures describing the handling of all written and oral complaints regarding drug products [21 CFR 211.198(a)];

(6) failure to justify the incubation of liquid bulk microbial samples for 24 hours, which is contrary to USP methodology of 48 to 72 hours [21 CFR 211.194(b)];

(7) failure to establish and assess the stability characteristics of drug products from batches in which product specifications were changed [21 CFR 211.166];

(8) failure to include representative labeling and/or package inserts in 10 of 35 batch production and control records reviewed [21 CFR 211.188(b)(8)].

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter of the steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action can not be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Charles H. Scarbrough, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Mr. Scarbrough.

Sincerely,

James E. Gamet
District Director
New Orleans District

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Enclosure: FDA-483

bcc: HFA-224
HFC-210 (CFN: 2319121)
HFI-35 (purged CHS)
HFD-300
HFR-SE1 RFDD
Warning Letter file
DIB
SJB/MWR
EI
Legal file
NOL-DO R/F
CB R/F